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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,501	09/02/2005	Igor Krisch	LR/G-32980A	4703
72554	7590	11/25/2008		
SANDOZ INC 506 CARNEFIE CENTER PRINCETON, NJ 08540			EXAMINER JAVANMARD, SAHAR	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			11/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,501	Applicant(s) KRISCH ET AL.	
	Examiner SAHAR JAVANMARD	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-29 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-18, 20-25, and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

This Office Action is in response to Applicant's remarks filed on 7/29/2008. Claim(s) 15-29 are pending. Claim(s) 19 and 26-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant's election without traverse of the restriction requirement in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL. Claim(s) 15-18, 20-25, and 29 are examined herein insofar as they read on the elected invention and species.

Response to Arguments

In view of Applicant's arguments with respect to the 103(a) rejection of claims 15-18, 20-22, and 24-25 as being unpatentable over Dackis et al. in view of Rucman et al., the rejection is hereby withdrawn.

In view of Applicant's arguments with respect to the 103(a) rejection of claims 23 as being unpatentable over Dackis et al. in view of Rucman et al. in further view of Glavan, the rejection is hereby withdrawn.

The following new rejection is made in the office action below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-18, 20-25, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pulvirenti et al. (Journal of Pharmacology and Experimental Therapeutics, 1998) in view of Glavan et al. (Molecular Pharmacology, 2002) of record in further view of Pulvirenti et al. (TiPS, 1994).

Pulvirenti (1998) teaches that a new class of drugs which possess a unique pharmacological profile on dopamine neurotransmission has been characterized,

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namely dopamine partial agonists. These drugs bind to the dopamine receptor with high affinity but low intrinsic activity. The functional consequence is that these compounds act as antagonists under conditions of high dopamine tone, such as in the case of intense presynaptic activity or after pharmacological stimulation (*e.g.*, after exposure to cocaine or amphetamine). Pulvirenti teaches that this presumably occurs because the low intrinsic activity of these compounds substitutes for the high-activity endogenous agonist at the receptor site. In contrast, in conditions of low dopamine tone such as after denervation or during functional depletion of the neurotransmitter, partial agonists show agonistic properties since their low intrinsic activity meets with a hyperresponsive receptor system (page 1231, columns 1 and 2 bridging paragraph).

Pulvirenti (1998) teaches that the aim of the present study was to characterize the effects of terguride on different aspects of cocaine self-administration in rats. Terguride is a prototype aminoergoline which acts as a partial agonist at the dopamine D2 receptor site (page 1232, column 1, 4th full paragraph).

Pulvirenti (1998) teaches that in light of these considerations, the decrease induced by terguride in the breaking point for cocaine self-administration measured in the progressive ratio schedule suggests that this partial dopamine agonist may reduce the reinforcing magnitude of cocaine (page 1235, column 2, 2nd full paragraph).

Further, the present data support the hypothesis that partial dopamine agonists may represent a novel therapeutic strategy for normalizing dopamine neurotransmission, a basic feature which may be of importance not only during the various phases of the natural history of drug dependence, but, possibly, in the course of

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other neuropsychiatric disorders characterized by still poorly controllable fluctuations of dopamine neurotransmission (page 1237, column 2, last paragraph).

Pulvirenti (1998) does not teach the dopamine agonist 9,10-didehydro-N-methyl-N-(2-propynyl)-6-methyl-8 β -aminomethylergoline (aka LEK-8829) and the dosage regimen thereof.

Glavan teaches the bimalate salt of 9,10-didehydro-N-methyl-N-(2-propynyl)-6-methyl-8 β -aminomethylergoline (page 360, column 2, lines 1-2) as partial dopamine agonists (abstract; page 360, column 2). Glavan teaches the administration of LEK-8829 at doses of 1.7 mg/kg (page 362, results section).

Pulvirenti (1994) teaches that there is much evidence that suggests that dopamine receptor partial agonists possess a unique pharmacological profile since their net effect depends on the level of existing synaptic activity (that is, the degree of concurrent receptor activity) and provides a rationale for testing the effects of these types of compounds in psychostimulant addiction (page 376, column 2, "partial agonists"). Further, it is disclosed that although dopamine receptor partial agonists produce amphetamine-like, but not cocaine-like, discriminative stimulus effects, they do not possess psychostimulating activity in naive animals, an effect that is observed with dopamine receptor agonists with abuse liability. This further supports the hypothesis that dopamine receptor partial agonists possess a unique pharmacological profile. Thus, in the presence of a physiological level of dopamine tone, partial agonists would be presumably devoid of abuse liability (page 377, column 2, last paragraph).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the administration of a partial dopamine agonist such as terguride as a method to of treating psychostimulant addiction as taught by Pulvirenti (1998) and to have also have used LEK-8829. Glavan teaches that LEK-8829 is a partial dopamine agonist. One would be motivated to also administer LEK-8828 as a method of treating psychostimulant addiction based on the teachings of Pulvirenti (1994). Pulvirenti (1994) discloses several examples of partial dopamine agonists that possess a unique pharmacological profile that would enable them to be effective in treating psychostimulant addiction. Thus it would be obvious to one of ordinary skill in the art to employ one dopamine agonist over another, in the absence of unexpected results. Furthermore, because of the structural similarity between terguride and LEK-8829, the skilled artisan would more likely make this substitution.

Conclusion

Claims 15-18 and 20-25 are not allowed.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sahar Javanmard whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617

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